REMARKS

According to the Office Action, three basic determinations were made by the Examiner. First, claims 36-47 have been withdrawn subject to a restriction requirement. Second, claims 1-18, 20-35, 48-54 and 58-63 were rejected as being anticipated by D'Antonio et al. U.S. Patent No. 6,056,716 under 35 U.S.C. 102(b). Third, the Examiner has rejected claims 19 and 55-58 as being obvious over D'Antonio et al. (U.S. Patent No. 6,056,716) under 35 U.S.C. 103(a). The claims have been amended as explained below, and are believed to be in allowable form for the reasons set forth hereafter. New claims 64-67 have been added, and it is believed that they are allowable as well.

U.S. Patent No. 6,056,716 (D'Antonio et al.) discloses a jet injector system for rapidly making jet injections by discharging an injectate through an exit nozzle into the subcutaneous region of the dermis of a body via a jet stream. D'Antonio et al. discloses an injectate container which is held by a housing. The forward portion of the housing faces the body being injected. The injection system of D'Antonio et al. found particular usage in the process of injecting large numbers of bodies, such as large numbers of cows, pigs, horses, etc., as well as humans. During these large numbers of injections, it was found that blood appeared at the injection site and on the forward part of the injecting device. The injection of animals and people thus led to the fear that health workers would become ill from the injecting process. Thus, health workers administering injections in mass immunizations to children, and those administering mass immunizations to animals, have become extremely sensitive to blood-borne pathogens. This is particularly true in view of the hectic nature of making these immunizations. In the device shown in D'Antonio et al., effective as it may be, the orifice end of the cartridge shown in Figs. 7A and 7B of the patent (and explained at col. 22, lines

57-67, and col. 23, lines 1-24 directly contacts the injector housing, and poses a risk of blood contacting the injector housing as the cartridge passes through the housing. Likewise, even though there is a guard ring provided to reduce the risk of splashing of the injectate, any blood present on the ring is nevertheless exposed and is in close proximity to the housing and/or health care worker when the cartridge is pulled away from the patient. With reference to the embodiment shown in Fig. 7E (and described at col. 25, lines 46-67, through col. 26, lines 1-6) of D'Antonio et al., a user must open the door to the barrel-like restraining chamber and insert a cartridge. The front end of the cartridge is in direct contact with the front end of the injector housing, and any blood on the guard ring when the cartridge is pulled away from the patient is subject to contact with the housing and with the user who is required to open the door so that the cartridge can be removed.

With reference to the embodiment shown in Figs. 7G, 7GG and 7GG' of D'Antonio et al., a multi-channel configuration is shown for delivering several medications simultaneously, or else one medication through several orifices. The user slides the barrel forward to insert cartridges and slides it back into position for the injection (as explained at col. 27, lines 3-9). When this is done in reverse after an injection, the used cartridges are slid out of the barrel exposing the user to any blood present on the external guard ring. A trap door like that shown in the embodiment of Fig. 7E (col. 27, lines 8–10) could be used which also could carry possible problem-causing blood.

The present invention as defined in most of the claims avoids the foregoing problem by in effect establishing a barrier to isolate any surfaces which could carry blood resulting from an injection from contact by a user of the hypodermic injection system. A brief discussion of the present application explaining the foregoing barrier, followed by a discussion of the relevant claims, follows.

With reference to the present application, it is explained on page 2, lines 7-10, that there is a great need to avoid contact by a user of the injection system with either the injectate or the injection

portion of the system. On page 3, lines 10-17, it is stated that the container members be disposable without requiring any physical contact or handling of the disposable portion by the user. On page 4, lines 14-18, an object of the invention is set forth for the provision of a hypodermic injection system which prevents the user from contacting potentially contaminated surfaces after an injection procedure. It is explained on page 5, lines 18 and 19, that the front plate in a preferred embodiment of the invention for holding cartridges is ejectable or catapulted from the injector after the cartridges have been used, and the plate with the spent cartridges is disposed.

Fig. 3 shows a view of a disposable front end of the front plate for holding injectate cartridges, as discussed on page 6, lines 6, 7, 26 and 27, and on page 7, lines 12-17. Fig. 4 shows a similar view, with a description on page 8, lines 19-22.

Claim 1 of the above-identified application in its amended form states that the hypodermic injection system incorporates a housing, a container-holding member for holding the containers and spacing them from the housing, and a latching and release apparatus for releasably latching and holding the container-holding member with the containers held thereby without any physical contact by the user, and spaces the front end of the holder from the housing. As stated in most of the claims, the container-holding member thus prevents contact of the housing with any contamination on the front end of the containers, and the latching and release apparatus disposes of the container-holding member without any physical contact by the user. As shown in Fig. 2 of the present invention, it should be clear that any injectate and blood which is in contact with the cartridges or front end of the container-holding member cannot contaminate the housing of the hypodermic injection system or the user since neither are contacted by the front end of the container-holding member after use. Accordingly, it is respectfully requested that claim 1 and its dependent claims 2-22 are therefore patentable over D'Antonio et al. with respect to 35 U.S.C. 102(b).

Claim 23 defines a hypodermic injection system comprising an injection housing with at least two cartridges, a holding member for holding the cartridges, a latching and release apparatus in or on the housing for releasably latching the holding member, a ram apparatus for moving plungers through the cartridges, a carriage for moving the ram apparatus at uniform pressures during an injection process, a spring apparatus for moving the carriage from the set position to the dispensing position, a carriage resetting apparatus and a releasable latching device for latching the spring apparatus for the carriage resetting apparatus. The holding member holds the cartridges spaced away from the housing so that the forward end of the cartridges does not physically contact the housing, and the latching and release apparatus spaces the front end of the holding member and the cartridges away from the housing, in both cases to avoid contamination of the housing by contaminants. This feature is not shown in D'Antonio et al. Accordingly, it is respectfully submitted that claim 23, and claims 24-35 which depend therefrom, are all allowable under 35 U.S.C. 102(b), because as explained above, D'Antonio et al. does not have a barrier for isolating either the cartridges or the cartridge holding member from the housing.

Claim 48 in its amended form also recites the isolation of the forward end of the container from the housing and the front end of the holding member from the housing. For the reasons discussed above, D'Antonio et al. does not disclose these features. It is, therefore, submitted that claim 48 is allowable pursuant to 35 U.S.C. 102(b), and such action is requested.

Claim 49 has limitations similar to those in claim 23 with regard to the isolation of the cartridges and the holding member from the housing, and for the reasons explained earlier, it is submitted to be allowable over D'Antonio et al. under 35 U.S.C. 102(b).

Claim 52 in its amended form differs from D'Antonio et al. in two basic ways. First, it defines the cartridge as having a rupturable seal dividing the holding portion defined by the plunger into two compartments. The system has a device for rupturing the seal. Second, the latching and

release apparatus is manually actuable, so that the user need not touch the spent cartridge to remove it. The latter provisions are not incorporated in D'Antonio et al.

Claim 53 has similar limitations to those described above, and it is further respectfully stated that claim 53 should be allowable under 35 U.S.C. 102(b). The foregoing should apply to claim 54 that depends from claim 53 and includes the limitations discussed above.

Independent claims 59, 61 and 63 likewise include the limitations that the holding member is held by the latching and release means so that neither the front end of the holding member nor the cartridges engage the housing, and they should be allowed pursuant to 35 U.S.C. 102(b) for the reasons set forth above with respect to the earlier claims.

The invention as defined in claim 62 states the latching and release apparatus is manually actuable so that the user need not touch the containers to remove them from the member. Also, the forward end of the container(s) does not contact the housing. These limitations are not found in D'Antonio et al.

Claims 19 and 55-58 stand rejected under 35 U.S.C. 103(a) as being obvious over D'Antonio et al. It is respectfully submitted that for the reasons stated above these claims are allowable with their parent claims in the present form. It is, accordingly, respectfully submitted that these claims are allowable as well.

New claims 64-79 have been added. Claim 64 does not isolate the front end of the holding member from the housing, but it does recite a ram apparatus for simultaneously forcing injectate from the cartridges. Claim 65 depends from claim 64 and defines the housing and the members housed therein. Dependent claim 66 provides the means for isolating the front end of the holding member from the housing. New claim 67 defines the hypodermic system of the invention, and defines both the isolation of the front end of the holding member from the housing and apparatus for simultaneously applying the force required to discharge injectate from the containers. New claims

68-79 all limit the latching and release apparatus to one that is manually actuable in claims 1, 23, 48, 49-51, 53, 59-61, 63 and 67. As explained above, a manually actuable latching and release member makes contact by the user of the container or cartridge unnecessary to remove the latter parts.

The claims defining the invention are believed to be allowable, and such action is respectfully requested.

The Examiner is invited to telephone the undersigned if a discussion of any outstanding issues in this application would expedite its prosecution.

Respectfully submitted,

By: _____
D. Peter Hochberg
Reg. No. 24,603

DPH/ck

Enc.: Petition and Fee for Extension of Time

D. Peter Hochberg Co., L.P.A.
1940 E. 6th Street - 6TH Floor
Cleveland, Ohio 44114
Phone: (216) 771-3800 / Fax: (216) 771-3804
e-mail: dphdocket1@aol.com

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

I hereby certify that this paper (along with any paper referred to as being attached hereto or transmitted herewith) is being deposited with the United States Postal Service as first class mail in an envelope addressed: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: October 23, 2003

_____
Christine A. Kotran